Complete Summary

GUIDELINE TITLE

Routine vitamin supplementation to prevent cancer and cardiovascular disease: recommendations and rationale.

BIBLIOGRAPHIC SOURCE(S)

Routine vitamin supplementation to prevent cancer and cardiovascular disease: recommendations and rationale. Ann Intern Med 2003 Jul 1;139(1):51-5. [42 references] <u>PubMed</u>

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Cancer
- Cardiovascular disease

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To summarize the U.S. Preventive Services Task Force recommendations on routine vitamin supplementation to prevent cancer and cardiovascular disease and the supporting evidence

TARGET POPULATION

Adults seen in primary care settings in the United States

Note: The U.S. Preventive Services Task Force did not review evidence regarding vitamin supplementation for patients with known or potential nutritional deficiencies, including pregnant and lactating women, children, the elderly, and people with chronic illnesses.

INTERVENTIONS AND PRACTICES CONSIDERED

Routine vitamin supplementation with:

- Vitamins A, C, or E
- Multivitamins with folic acid
- Antioxidant combinations
- Beta-carotene

MAJOR OUTCOMES CONSIDERED

Key Question for Cancer: Do antioxidant vitamin supplements reduce all-cause mortality, cancer mortality, or the incidence of cancer or certain precancerous lesions in the general adult population of the United States?

Key Question for Cardiovascular Disease: Does supplementation with vitamin A, vitamin C, vitamin E, beta-carotene, or a multivitamin reduce cardiovascular death, all-cause mortality, or cardiovascular events in the general adult population of the United States and in a population with evidence of atherosclerotic heart disease?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): Systematic evidence reviews were prepared by the Oregon Health & Science University Evidence-based Practice Center (EPC) for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Inclusion/Exclusion Criteria for Admissible Evidence

Cancer Literature

The criteria for inclusion in the review were developed in consultation with members of the USPSTF. English-language randomized controlled trials and prospective cohort studies concerning adults in developed countries were eligible for inclusion. Case-control studies were excluded unless they were performed in the context of a prospective cohort study (i.e., a nested case-control study). Studies of supplementation with vitamin A, vitamin C, vitamin E, beta-carotene, folic acid, combinations of these vitamins, or a multiple vitamin were eligible if they reported a) the incidence of or mortality from any invasive cancer other than nonmelanoma skin cancer or b) the incidence of colonic polyps. Studies of other precancerous lesions, carcinoma in situ, and regression of cancer or of precancerous lesions were excluded.

The report included the results of review of randomized trials that addressed the key question. The results of cohort studies were presented to the USPSTF, but they were excluded from the report because they did not contribute to the Task Force's recommendations.

Cardiovascular Literature

The scope of this review was developed with input from the USPSTF. The Oregon Health & Science University Evidence-based Practice Center (EPC) staff included reports of randomized trials and prospective cohort studies from U.S. and European populations that assessed use of vitamin supplements and reported the incidence of or death from cardiovascular events. The EPC staff included only studies that measured intake of vitamins from supplements, not from foods; most supplements provide single or limited nutrient combinations whereas dietary sources are nutritionally complex in nature and complicate data interpretation. Only cohorts that reported specifically on vitamin supplement use with risk ratios independent of dietary intake were included. Both primary and secondary prevention trials were considered, but were analyzed separately. Studies conducted in specific populations that were not widely generalizable were excluded, such as a cohort with end-stage renal disease. Only cohort studies rated as being of good to fair quality by predetermined criteria from a system developed by the current USPSTF were included. Studies were excluded if they contained no original data, were not relevant (e.g., addressed vitamin deficiency disease), did not report data on the specified outcomes, or took place in an acute care setting. Case-control studies were excluded because of retrospective data collection.

Search Strategy

Cancer Literature

The Cochrane Controlled Trials Registry (December, 2001) and the MEDLINE database from 1966 to December, 2001 were searched using terms for the 5 nutrients (A, C, E, beta-carotene, and folate) as well as multivitamin and antioxidant supplements and terms for cancer and precancerous lesions. The reference lists of review articles were also searched and, in several rounds of review of earlier manuscripts, experts were asked for additional references. MEDLINE was searched again (December 2001) using the acronyms or full titles of the major trials and cohort studies to identify additional publications.

A supplemental electronic search was performed to update the literature review through the end of 2002. The search was limited to publications in English and studies involving human subjects. The MEDLINE search terms included precancerous conditions, neoplasms, antioxidants, vitamins/administration and dosage, and vitamins/therapeutic use, as well as "randomized" or "controlled" or "clinical" trial.

Cardiovascular Literature

The Cochrane Controlled Trials Registry and MEDLINE were searched for relevant papers published in English from 1966 to September 2001, using Medical Subject Headings and keywords for the individual nutrients (vitamin A, vitamin C, vitamin E, beta-carotene, folic acid), and for multivitamin and antioxidant supplements, combined with terms for cardiovascular disease (CVD), coronary artery disease, myocardial infarction, and related risk factors (blood pressure, hypertension, hyperlipidemia, homocysteine). The EPC staff examined reference lists of review articles and asked experts for additional references. Finally, MEDLINE was searched using the acronyms or full titles of the major trials and cohort studies to identify additional publications.

Study Selection

Two reviewers applied the eligibility criteria listed above after reviewing the titles and abstracts of retrieved citations and again after selecting full-text articles for closer review.

NUMBER OF SOURCE DOCUMENTS

Key Question for Cancer: Ten randomized, controlled trials (RCTs) were included from the first literature search. From the supplemental literature search, ten studies met the inclusion criteria. Two studies were new randomized controlled trials that were not included in the earlier review, and the remaining eight were follow-up studies of two large clinical trials.

Key Question for Cardiovascular Disease: 38 articles, representing ten cohort studies and twenty randomized, controlled trials, were selected for inclusion in evidence tables. An additional 25 articles were included for background and context.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The Task Force grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): Systematic evidence reviews were prepared by the Oregon Health & Science University Evidence-based Practice Center (EPC) for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Evidence Abstraction

Cancer Literature

Two reviewers independently abstracted descriptive data from the included trials, using one form for abstraction of information about the study design and another form for results. To assess study quality, the EPC staff used the system developed by the USPSTF, which includes a set of 6 criteria to rate the internal validity of each study as "good," "fair," or "poor." For clinical trials, study quality was assessed using the Jadad score. The summarized results of studies were organized in evidence tables by type of study, nutrient, and outcome. For supplement/outcome combinations with sufficient evidence, the EPC staff

assessed heterogeneity among studies and conducted meta-analyses using a pairwise, sequential procedure based on maximum likelihood methods.

Cardiovascular Literature

The EPC staff abstracted the following descriptive information: population, setting, sample size, supplement (dose, formulation, and frequency), control group intervention, length of follow-up, follow-up rate, confounding factors, factors controlled for in analyses, method of ascertaining compliance, compliance rate, and adverse effects. They also recorded data on the following outcomes: cardiovascular events, myocardial infarction, restenosis, change in angina, cardiovascular mortality, and all-cause mortality. Study quality was assessed using the standards of the current USPSTF system. For randomized controlled trials, study quality was summarized using the Jadad score, which rates trials on a scale of 1 to 5 on the basis of adequacy of randomization method, blinding, and other criteria. Data abstraction and quality assessment were conducted independently by at least 2 reviewers. Disagreements were resolved by consensus or by a third reviewer. Finally, the EPC staff summarized the strength, level, and quality of the overall evidence tables for the effectiveness of each of the vitamin supplements to prevent cardiovascular disease (CVD).

Preparation of the Systematic Evidence Reviews

AHRQ staff and USPSTF members participated in the initial design of the study and reviewed interim analyses and the final manuscripts for both Systematic Evidence Reviews.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When the overall quality of the evidence is judged to be good or fair, the U.S. Preventive Services Task Force (USPSTF) proceeds to consider the magnitude of net benefit to be expected from implementation of the preventive service. Determining net benefit requires assessing both the magnitude of benefits and the magnitude of harms and weighing the two.

The USPSTF classifies benefits, harms, and net benefits on a 4-point scale: "substantial," "moderate," "small," and "zero/negative."

"Outcomes tables" (similar to 'balance sheets') are the USPSTF's standard resource for estimating the magnitude of benefit. These tables, prepared by the topic teams for use at USPSTF meetings, compare the condition specific outcomes expected for a hypothetical primary care population with and without use of the preventive service. These comparisons may be extended to consider only people of specified age or risk groups or other aspects of implementation. Thus,

outcomes tables allow the USPSTF to examine directly how the preventive services affects benefits for various groups.

When evidence on harms is available, the topic teams assess its quality in a manner like that for benefits and include adverse events in the outcomes tables. When few harms data are available, the USPSTF does not assume that harms are small or nonexistent. It recognizes a responsibility to consider which harms are likely and judge their potential frequency and the severity that might ensue from implementing the service. It uses whatever evidence exists to construct a general confidence interval on the 4-point scale (e.g., substantial, moderate, small, and zero/negative).

Value judgments are involved in using the information in an outcomes table to rate either benefits or harms on the USPSTF´s 4-point scale. Value judgments are also needed to weigh benefits against harms to arrive a rating of net benefit.

In making its determinations of net benefit, the USPSTF strives to consider what it believes are the general values of most people. It does this with greater confidence for certain outcomes (e.g., death) about which there is little disagreement about undesirability, but it recognizes that the degree of risk people are willing to accept to avert other outcomes (e.g., cataracts) can vary considerably. When the USPSTF perceives that preferences among individuals vary greatly, and that these variations are sufficient to make trade-off of benefits and harms a 'close-call', then it will often assign a C recommendation (see the "Recommendation Rating Scheme" field). This recommendation indicates the decision is likely to be sensitive to individual patient preferences.

The USPSTF uses its assessment of the evidence and magnitude of net benefit to make recommendations. The general principles the USPSTF follows in making recommendations are outlined in Table 5 of the companion document cited below. The USPSTF liaisons on the topic team compose the first drafts of the recommendations and rationale statements, which the full panel then reviews and edits. Recommendations are based on formal voting procedures that include explicit rules for determining the views of the majority.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr; 20(3S): 21-35.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

Α

The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

В

The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

С

The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D

The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

I

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

<u>Peer Review</u>. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations

are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the whole USPSTF before final recommendations are confirmed.

Recommendation of Others. Recommendations for routine vitamin supplementation from the following groups were discussed: the American Academy of Family Physicians; the Canadian Task Force on Preventive Health Care; the American Cancer Society and the American Heart Association.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and the quality of the overall evidence for a service (good, fair, poor). The definitions of these grades can be found at the end of the "Major Recommendations" field.

The USPSTF concludes that the evidence is insufficient to recommend for or against the use of supplements of vitamins A, C, or E; multivitamins with folic acid; or antioxidant combinations for the prevention of cancer or cardiovascular disease. I recommendation.

The USPSTF found poor evidence to determine whether supplementation with these vitamins reduces the risk for cardiovascular disease or cancer. The available evidence from randomized trials is either inadequate or conflicting, and the influence of confounding variables on observed outcomes in observational studies cannot be determined. As a result, the USPSTF could not determine the balance of benefits and harms of routine use of supplements of vitamins A, C or E; multivitamins with folic acid; or antioxidant combinations for the prevention of cancer or cardiovascular disease.

The USPSTF recommends against the use of beta-carotene supplements, either alone or in combination, for the prevention of cancer or cardiovascular disease. D recommendation.

The USPSTF found good evidence that beta-carotene supplementation provides no benefit in the prevention of cancer or cardiovascular disease in middle-aged and older adults. In 2 trials restricted to heavy smokers, beta-carotene supplementation was associated with higher incidence of lung cancer and higher all-cause mortality. The USPSTF concludes that beta-carotene supplements are unlikely to provide important benefits and might cause harm in some groups.

Clinical Considerations

 The USPSTF did not review evidence regarding vitamin supplementation for patients with known or potential nutritional deficiencies, including pregnant and lactating women, children, the elderly, and people with chronic illnesses. Dietary supplements may be appropriate for people whose diet does not provide the recommended dietary intake of specific vitamins. Individuals may

- wish to consult a health care provider to discuss whether dietary supplements are appropriate.
- With the exception of vitamins for which there is compelling evidence of net harm (e.g., beta-carotene supplementation in smokers), there is little reason to discourage people from taking vitamin supplements. Patients should be reminded that taking vitamins does not replace the need to eat a healthy diet. All patients should receive information about the benefits of a diet high in fruits and vegetables, as well as information on other foods and nutrients that should be emphasized or avoided in their diet (see 2002 USPSTF recommendations on counseling to promote a healthy diet).
- Patients who choose to take vitamins should be encouraged to adhere to the dosages recommended in the Dietary Reference Intakes (DRI) of the Institute of Medicine. Some vitamins, such as A and D, may be harmful in higher doses; therefore, doses greatly exceeding the Recommended Dietary Allowance (RDA) or Adequate Intake (AI) should be taken with care while considering whether potential harms outweigh potential benefits. Vitamins and minerals sold in the United States are classified as "dietary supplements," and there is a degree of quality control over content if they have a U.S. Pharmacopeia (USP) seal. Nevertheless, imprecision in the content and concentration of ingredients could pose a theoretical risk not reflected in clinical trials using calibrated compounds.
- The adverse effects of beta-carotene on smokers have been observed primarily in those taking large supplemental doses. There is no evidence to suggest that beta-carotene is harmful to smokers at levels occurring naturally in foods.
- The USPSTF did not review evidence supporting folic acid supplementation among pregnant women to reduce neural tube defects. In 1996, the USPSTF recommended folic acid for all women who are planning, or capable of, pregnancy (see 1996 USPSTF information on screening for neural tube defects).
- Clinicians and patients should discuss the possible need for vitamin supplementation when taking certain medications (e.g., folic acid supplementation for those patients taking methotrexate).

Definitions:

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

Α

The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

В

The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

С

The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D

The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

L

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

The Task Force grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

CLINICAL ALGORITHM(S)

Not applicable

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is identified in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The U.S. Preventive Services Task Force (USPSTF) found poor evidence to determine whether supplementation with the vitamins A, C or E; multivitamins with folic acid; or antioxidant combinations reduces the risk for cardiovascular disease or cancer. The available evidence from randomized trials is either inadequate or conflicting, and the influence of confounding variables on observed outcomes in observational studies cannot be determined. As a result, the USPSTF could not determine the balance of benefits and harms of routine use of these vitamins supplements.

POTENTIAL HARMS

There are several known adverse effects caused by excessive doses of vitamins; for example, moderate doses of vitamin A supplements may reduce bone mineral density, and high doses may be hepatotoxic or teratogenic. A small but significant increase in lung cancer mortality observed in trials of smokers has been ascribed to beta-carotene supplementation; adverse effects of beta-carotene supplementation on non-smokers have not been observed on other trials. The adverse effects of vitamin supplementation were not reported in most studies reviewed by the U.S. Preventive Services Task Force. More studies are needed to better understand the harms of vitamin supplementation.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The U.S. Preventive Services Task Force (USPSTF) recommendations are independent of the U.S. government. They do not represent the views of the Agency for Healthcare Research and Quality (AHRQ), the U.S. Department of Health and Human Services, or the U.S. Public Health Service.
- The value of vitamins naturally occurring in food, the use of vitamin supplements for the prevention of other conditions (e.g., neural tube defects), and the use of vitamin supplements for the secondary prevention of complications in patients with existing disease are outside the scope of these guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing

clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Neither the resources nor the composition of the U.S. Preventive Services Task Force equip it to address these numerous implementation challenges, but a number of related efforts seek to increase the impact of future U.S. Preventive Services Task Force reports. The U.S. Preventive Services Task Force convened representatives from the various audiences for the Guide "Put Prevention Into Practice. A Step-by-Step Guide to Delivering Clinical Preventive Services: A Systems Approach"--clinicians, consumers and policy makers from health plans, national organizations and Congressional staff--about how to modify the content and format of its products to address their needs. With funding from the Robert Wood Johnson Foundation, the U.S. Preventive Services Task Force and Community Guide effort have conducted an audience analysis to further explore implementation needs. The Put Prevention into Practice initiative at the Agency for Healthcare Research and Quality (AHRQ) has developed office tools such as patient booklets, posters, and handheld patient mini-records, and a new implementation guide for state health departments.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the third edition of the Guide to Clinical Preventive Services. Freed from having to serve as primary repository for all of U.S. Preventive Services Task Force work, the next Guide may be much slimmer than the almost 1000 pages of the second edition.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit

from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals and test results are not always centralized.

RELATED QUALITY TOOLS

- Pocket Guide to Good Health for Adults
- A Step-by-Step Guide to Delivering Clinical Preventive Services: A Systems Approach
- Routine Vitamin Supplementation to Prevent Cancer and Cardiovascular Disease. What's New from the USPSTF.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

LOM DOMALN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Routine vitamin supplementation to prevent cancer and cardiovascular disease: recommendations and rationale. Ann Intern Med 2003 Jul 1;139(1):51-5. [42 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jul 1

GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

GUI DELI NE DEVELOPER COMMENT

The U.S. Preventive Services Task Force (USPSTF) is a Federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: Alfred O. Berg, MD, MPH (Chair); Janet D. Allan, PhD, RN, CS (Vice-chair); Paul Frame, MD; Charles J. Homer, MD, MPH*; Mark S. Johnson, MD, MPH; Jonathan D. Klein, MD, MPH; Tracy A. Lieu, MD, MPH*; Cynthia D. Mulrow, MD, MSc*; C. Tracy Orleans, PhD; Jeffrey F. Peipert, MD, MPH*; Nola J. Pender, PhD, RN*; Albert L. Siu, MD, MSPH; Steven M. Teutsch, MD, MPH; Carolyn Westhoff, MD, MSc; Steven H. Woolf, MD, MPH

*Members of the Task Force at the time this recommendation was finalized.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task force has an explicit policy concerning conflict of interest. All members and evidence-based practice center (EPC) staff disclose at each meeting if they have an important financial conflict for each topic being discussed. Task Force members and EPC staff with conflicts can participate in discussions about evidence, but members abstain from voting on recommendations about the topic in question.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr; 20(3S): 21-35.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>U.S. Preventive Services Task Force</u> (<u>USPSTF</u>) Web site and the <u>National Library of Medicine's Health</u> Services/Technology Assessment Text (HSTAT) Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Evidence Reviews:

- Morris C, Carson S. Routine vitamin supplementation to prevent cardiovascular disease: summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med. 2003. Jul; 139(2):56-69.
- Ritenbaugh C, Streit K, Helfand M. Routine vitamin supplementation to prevent cancer: a summary of the evidence from randomized control trials for the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2003. 36 p.
- Shetty P, Atkins D. Routine Vitamin supplementation to prevent cancer: update of evidence from randomized controlled trials, 1999-2002. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2003. 16 p.

Electronic copies: Available from the <u>U.S. Preventive Services Task Force</u> (USPSTF) Web site.

Background Articles:

- Woolf SH, Atkins D. The evolving role of prevention in health care: contributions of the U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr; 20(3S):13-20.
- Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr; 20(3S): 21-35.
- Saha S, Hoerger TJ, Pignone MP, Teutsch SM, Helfand M, Mandelblatt JS. The
 art and science of incorporating cost effectiveness into evidence-based
 recommendations for clinical preventive services. Cost Work Group of the
 Third U.S. Preventive Services Task Force. Am J Prev Med 2001
 Apr; 20(3S): 36-43.

Electronic copies: Available from <u>U.S. Preventive Services Task Force (USPSTF) Web site</u>.

Additional Implementation Tools:

• A step-by-step guide to delivering clinical preventive services: a systems approach. Rockville (MD): Agency for Healthcare Research and Quality

(AHRQ), 2001. 189 p. (Pub. No. APPIP01-0001). Electronic copies available from the AHRQ Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrg.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

- The Preventive Services Selector, an application for Palm Pilots and other PDA's, is also available from the AHRQ Web site.
- Routine vitamin supplementation to prevent cancer and cardiovascular disease. What's new from the third USPSTF. Rockville (MD): Agency for Healthcare Research and Quality; 2003 Jun. Electronic copies: Available from USPSTF Web site.

PATIENT RESOURCES

The following is available:

• The Pocket Guide to Good Health for Adults. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003.

Electronic copies: Available from the <u>U.S. Preventive Services Task Force</u> (<u>USPSTF</u>) Web site. Copies also available in Spanish from the <u>USPSTF Web site</u>.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on June 24, 2003. This summary was verified by the developer on June 26, 2003.

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